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...a non-profit institute dedicated to advancing the public health by providing a neutral forum for critical examination of the laws, regulations, and policies related to drugs, medical devices, other healthcare technologies, and foods.

Murray A. Lumpkin, M.D., M.Sc.
Senior Associate Commissioner
International Activities and Strategic Initiatives
Food and Drug Administration, HF-2
5600 Fishers Lane
Rockville, MD 20857-1706

Dear Dr. Lumpkin,

I appreciate the opportunity to submit comments to the record of the Combination Products meeting on November 25, 2002.

There are few examples of truly successful combination products, i.e. products that incorporate the qualities and use intents of two different technologies or classes, e.g. drug and medical device, biologic and medical device, drug and food. Medical foods are not combinations of food and drugs, but they may embrace the intents of both product classes. Dietary supplement products often imply, in their labelling and advertising, a combination of intents, but they do not meet the commonly accepted definition of combination products either.

Combination products are difficult for FDA. The legislation (FDCA) never contemplated combinations and establishes clear requirements for marketing food, drugs, biologics, medical devices, etc. Combinations of products within the same category are addressed in regulation and are common. "Interclass" combination products are not addressed.

"Interclass" combination products may be thought of like a pair of Siamese twins joined at the hip. Each has its own heart, mind and personal characteristics, but they must act in concert with the other. Society has difficulty dealing successfully with the needs of Siamese twins and, as a result, they rarely flourish.

Combination products that require compliance with the requirements of two distinct product classes may be a short-term necessity, but it is not the long-term path to success. Current law, regulation, culture and practice will not allow unbiased, efficient evaluation and approval of proposals for combination products. Complying with the standards for approval of two product classes is difficult, cumbersome and is not the answer.

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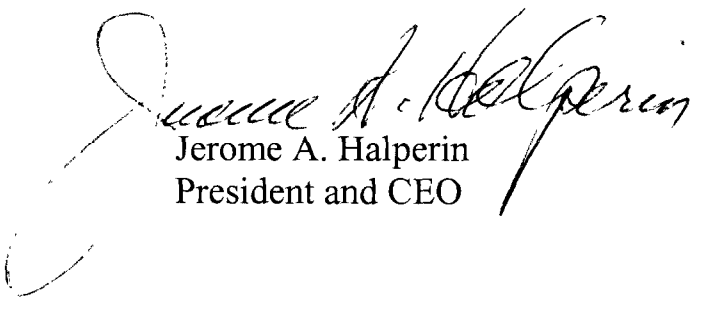
1000 Vermont Avenue, N.W., Suite 200 • Washington, DC 20005
(202) 371-1420 • Fax: (202) 371-0649 • e-mail: comments@fdli.org • Url: http://www.fdli.org

New technologies, i.e. technologies not currently addressed in current law (nanotechnology products will certainly fall into this category) will embrace the characteristics of more than one product class simultaneously, but will be so different from the current product classes that they will force the agency to review them not as a drug, device or biologic, but as an entity that inherently incorporates some of characteristics of two or more of these product classes, but is not a combination of them. They will have to be evaluated for what they are, i.e. multifunctional products.

The short-term solution is obvious. Use the current system to its best advantage and make the review process as facile as it can be. The long-term solution will require legislative and administrative remedies to create the legal and administrative frameworks to deal with new products of existing technologies fluidly and to address the opportunities of new technologies and inherently multifunctional products efficiently.

Sincerely yours,



Jerome A. Halperin
President and CEO